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Attorney Docket No.: 5051-445 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Moyer et al.
Application No.: 09/912,072
Filed: July 24, 2001
For: *Identification of Poinsettia Cultivars*

Confirmation No.: 3267
Group Art Unit: 1634
Examiner: S. Bausch

Submittal of:
- **Cover page (1 page)**
- **Appellant's Supplemental Brief on Appeal (20 pages)**
- **Appendix A (7 pages)**
- **Appendices B & C (3 pages)**

Total pages: 31

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APPELLANT'S SUPPLEMENTAL BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

Sir:

This Appeal Brief is filed pursuant to the "Notice of Non-Compliant Appeal Brief" mailed August 8, 2007 and the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed on November 27, 2006.

Appellant notes that the Appeal fee was paid with the Appeal Brief of January 29, 2007. Accordingly, **no additional fee is believed due**. However, any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220

REAL PARTY IN INTEREST

The real party in interest North Carolina State University (NCSU), the assignee of the rights to this application by virtue of assignment from the inventors to NCSU, recorded at the United States Patent and Trademark Office on January 7, 2002 on Reel 012444, Frame 0066.

RELATED APPEALS AND INTERFERENCES

Appellants are aware of no related appeals or interferences that would be affected by the present appeal.

STATUS OF CLAIMS

Claims 1-7, 10, 11, 21-24, 27-30, 52, 63, 64 and 69 are pending in the present application as of the filing date of this Appeal Brief. In order to reduce the issues to be considered on appeal, appellants have canceled claims 70-74 herein without prejudice or disclaimer. As of the filing date of this Appeal Brief, claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 remain rejected under 35 U.S.C. § 103(a) and claims 2, 4, 10, 11, 22, 27-29, 52 and 64 remain objected to for being dependent on rejected claims.

Appellants appeal the rejection of claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69. A copy of claims 1-7, 10, 11, 21-24, 27-30, 52, 63, 64 and 69 is attached hereto as **Appendix A**, presenting the claims at issue as twice rejected in the Final Office Action dated August 2, 2006.

STATUS OF AMENDMENTS

All amendments made by Appellants during prosecution are believed to be entered as indicated by the Final Office Action dated August 2, 2006.

SUMMARY OF CLAIMED SUBJECT MATTER

Ornamental plants such as begonias, geraniums, impatiens, poinsettias and the like comprise a large and profitable market in the United States. Many ornamental plants such as poinsettias are vegetatively or clonally propagated (*i.e.*, by cuttings from stock plants). Plants produced in this manner share the same genetic and phenotypic characteristics of the stock plant. Distributors, growers and buyers of ornamental plants are often concerned about the authenticity of the particular variety or cultivar of plant being grown or sold. Accordingly, a need exists for a method to reliably and accurately determine if a particular plant is the same cultivar as another cultivar, or if a particular plant is a member of a particular family or breeding program of plants.

Over the past 10 years, genetic mapping technologies utilizing analyses of restriction fragment length polymorphisms (RFLP), random amplified polymorphic DNA (RAPD), simple sequence repeats (SSR) and amplified fragment length polymorphisms (AFLP) have been used for identifying genetic markers for desirable traits or phenotypes in plants. These techniques have also been useful adjuncts to genetic and breeding programs for genome

mapping and marker-assisted selection, respectively. Using these technologies, attempts have been made to develop cultivar-specific fingerprints for identification.

Unfortunately, the RAPD and RFLP technologies used in previous attempts to fingerprint cultivars lacked the resolution to distinguish between genotypes. While AFLP and SSR techniques generally have sufficient resolution to distinguish between certain genotypes, these methods have heretofore been unable to overcome the problems posed by the inherent heterogeneity in regions of plant genomes that contain polymorphisms, but which are unrelated to the regions of the genomes that are related to cultivar identity. In particular, these technologies have been limited in their use for reliable cultivar identification of vegetatively propagated plants due to recognized and unrecognized regions of heterogeneity in these plant genomes.

The present inventors have examined over 100 amplified restriction fragments that exhibit polymorphisms between cultivars of the Poinsettia genome, a clonally propagated crop. In particular, the inventors have identified amplified restriction fragments that are polymorphic between genotypes, and which in specific combinations also correlate with cultivar identity. The discovery of regions of the genome that are involved in cultivar differentiation (as distinguished from those that appear as polymorphisms but are in fact not related to cultivar identity) provides an advantageous and significant advancement for the genomic fingerprinting of plants generally, and more specifically of vegetatively propagated plants such as poinsettias.

The present application includes independent claims 1, 3, 21, 63 and 69. Claim 1 is directed to a method of estimating a genetic relationship, if any, between a poinsettia plant and a known poinsettia cultivar, by obtaining a DNA fingerprint of the poinsettia plant's genomic DNA by AFLP, the fingerprint being a collection of amplified restriction fragments; comparing the fingerprint so obtained with a genomic DNA fingerprint of the known poinsettia cultivar; and estimating the genetic relationship between the poinsettia plant and the known cultivar by determining the degree of similarity, if any, between the fingerprints. (*See* Specification, for example, at least on page 4, lines 14-24).

Claim 3 is directed to a method of assessing the breeding history of a first poinsettia plant. This method also involves obtaining a DNA fingerprint of the genomic DNA of a first poinsettia plant, where the fingerprint comprises a set of amplified restriction fragments. The fingerprint of the first poinsettia plant is compared with a fingerprint of the genomic DNA of

the second poinsettia plant that is a representative member of a specific breeding family, where the fingerprint comprises a set of amplified restriction fragments. A profile index value is generated based on the comparison of the fingerprint of the first poinsettia plant with the fingerprint of the poinsettia plant that is a representative member of a specific breeding family. Known mathematical models may be used to determine whether the two poinsettia plants belong to a representative breeding family. (*See* Specification, for example, at least on page 4, lines 14-24).

Claim 21 is directed to a method of determining the degree of similarity of a first poinsettia plant to a second poinsettia plant, by obtaining a DNA fingerprint of the genomic DNA of a first poinsettia plant by AFLP, wherein the fingerprint comprises a set of amplified restriction fragments; comparing the fingerprint of the first poinsettia plant with a fingerprint of the genomic DNA of the second poinsettia plant, wherein the fingerprint comprises a set of amplified restriction fragments; and generating a profile index value based on the comparison of the fingerprint of the first poinsettia plant with the fingerprint of the second plant, wherein a profile similarity index value of about 1 or a dissimilarity value of about zero indicates that the two poinsettia plants are genetically similar. (*See* Specification, for example, at least on page 4, lines 25-34 through page 5, lines 1-16).

Claim 63 is directed to a method of determining whether a poinsettia plant is a representative of a known poinsettia cultivar, by obtaining a first DNA fingerprint of the genomic DNA of a poinsettia plant by AFLP analysis, and then comparing the first fingerprint with a second fingerprint of the genomic DNA of the known poinsettia cultivar; wherein the poinsettia plant is a representative of the known poinsettia cultivar if the fingerprint of the poinsettia plant and the fingerprint of the known poinsettia cultivar have the same complement of polymorphic bands. *See* Specification, for example, at least on page 7, lines 1-8.

Claim 69 is directed to a method of distinguishing a poinsettia cultivar from a known poinsettia cultivar, by obtaining a first DNA fingerprint of the genomic DNA of a poinsettia plant by AFLP analysis and then comparing the first fingerprint with a fingerprint of the genomic DNA of the known poinsettia cultivar, wherein the poinsettia plant is not a representative of the known poinsettia cultivar if the fingerprint of the poinsettia plant and the fingerprint of the known poinsettia cultivar are not essentially the same. (*See* Specification, for example, at least on page 8, lines 3-10).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 3, 5-7, 21, 23, 24, 63 and 69 are properly rejected as unpatentable under 35 U.S.C. § 103(a) over Ling et al. (*HortSci* 32: 122-124 (1997)), in view of Loh et al. (*Annals of Bot.* 84:155-161 (1999)) as defined by Dice et al. (*Ecology* 26:297-302 (1945)).

2. Whether claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are properly rejected as unpatentable under 35 U.S.C. § 103(a) over Ling et al. in view of Barcaccia et al. (*J. Horticultural Science and Biotechnology* 74:243-50, (1999)) as defined by Dice et al.

3. Whether claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are properly rejected as unpatentable under 35 U.S.C. § 103(a) over Ling et al. in view of Sukhwinder et al. (*Crop Improvement* 25:15-20 (1998)) as defined by Dice et al.

4. Whether claims 1, 3, 5, 6, 21, 23, 30, 63 and 69 are properly rejected as unpatentable under 35 U.S.C. § 103(a) over Ling et al. in view of Barker et al. (*Genome* 42:173-183 (1999)) as defined by Tullos (Offprint from Palm and Chapel, eds., (1997)).

ARGUMENT

I. Legal Standard of Obviousness

A determination under 35 U.S.C. § 103(a) that an invention would have been obvious to someone of ordinary skill in the art is a conclusion of law based on fact. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S.Ct. 2187. The Patent Office has the initial burden under §103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, the Patent Office must satisfy three requirements. First, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *See In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art"), *see also Princeton Biochemicals, Inc., v. Beckman Coulter, Inc.*, 411

F.3d 1332, 1337 (Fed. Cir. 2005). Furthermore, the teachings must come from the prior art, not from the Appellant's disclosure. *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some teaching or suggestion that would have motivated the skilled artisan to modify a reference or to combine references. *Iron Grip Barbell Co., Inc., v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004), (*see also In re Fine*, 837 F.2d 1071, 1075 (Fed.Cir.1988) (teachings of a reference can be combined only if there is some suggestion or incentive to do so) (emphasis in the original). Such a requirement prevents a hindsight-based obviousness analysis based on the inventor's disclosure. *Ecolochem Inc., v. So. Cal. Edison Co.* 227 F.3d 1361, 1371-72 (Fed. Cir. 2000). In addition, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. §2143.01, citing *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990).

As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be ***clear and particular*** and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999), *see also In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed).

The third requirement to establish a *prima facie* case of obviousness is that the proposed modification or combination of the prior art must provide a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991); *see also In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

In the present case, a *prima facie* case of obviousness has not been established with regard to the combinations of presently cited references. No clear and particular evidence has been presented from the prior art that provides any motivation to combine. Further, no evidence has been presented from the prior art that one of ordinary skill in the art at the time the invention was made would have considered the proposed combinations to have any

reasonable expectation of success. Thus, the outstanding rejections fail to satisfy the Office's burden necessary to maintain an obviousness rejection.

II. **Claims 1, 3, 5-7, 21, 23, 24, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al. (*HortSci* 32: 122-124 (1997)), in view of Loh et al. (*Annals of Bot.* 84:155-161 (1999)) as defined by Dice et al. (*Ecology* 26:297-302 (1945)).**

The Final Office Action dated August 2, 2007 maintains the rejection of claims 1, 3, 5-7, 21, 23-24, 63 and 69 as allegedly unpatentable under 35 U.S.C. § 103(a) for obviousness over Ling et al. in view of Loh et al. (*Annals of Botany* 84:155-61, 1999) as further defined by Dice. Final Action, page 5. According to the Final Action, "Ling et al. teaches a method of distinguishing genetic relationship and diversity between Poinsettia cultivars, including breeding family 'Freedom'." Final Action, page 5. The Final Action further states that "Loh et al. teach a method using AFLP marker protocol to identify and study intra-and inter-specific variations in *Caladium bicolor* cultivars, an ornamental asexual plant," and that "Loh et al. teach using AFLP markers is useful in differentiating and characterizing cultivars within a *Caladium* species." Final Action, page 6-7. The Action concludes that it would have been "obvious to one of skill in the art at the time the invention was made to improve the method of identifying poinsettia cultivars by RAPD markers taught by Ling et al. to include the AFLP marker assay as taught by Loh et al." and that the "ordinary artisan would have had a reasonable expectation of success in using AFLP marker assay taught by Loh et al. in the method taught by Ling et al. of Poinsettia cultivar genetic analysis because Loh et al. teach using AFLP marker to identify inter- and intra-cultivars in *C. bicolors*, an ornamental asexual plant, like that of Poinsettia cultivars....." Final Action, page 7. Applicants respectfully disagree.

The Ling et al. reference does not disclose or suggest a method of estimating a genetic relationship between poinsettia plants, a method of determining the profile similarity between a poinsettia plant and a known poinsettia cultivar, a method of assessing the breeding history of a poinsettia plant, a method of determining whether a poinsettia plant is a representative of a known poinsettia cultivar, or a method of distinguishing a poinsettia cultivar from a known poinsettia cultivar using AFLP analysis as recited by the present claims. As conceded by the outstanding rejection, Ling et al. concerns RAPD analysis. Further, Ling et al. uses RAPD

analysis to compare the DNA of poinsettia cultivars from widely differing groups and as a result the RAPD markers used would not have to have been robust to distinguish these cultivars. (*See* Moyer Declaration, para. 4, submitted concurrently with the response dated May 23, 2005; hereinafter "the Moyer Declaration") (copy enclosed at Appendix B). Accordingly, Ling et al., alone or in any combination, does not render obvious the present invention utilizing AFLP analysis to distinguish among and between closely related poinsettia cultivars.

The outstanding rejection is based on the premise that Loh et al. provides the motivation for one of ordinary skill in the art to apply AFLP analysis to poinsettia because Loh et al. used this technique to evaluate *Caladium* cultivars. However, there is absolutely no suggestion in the cited Loh et al. publication that AFLP analysis could be applied to poinsettia or even a more general statement that AFLP analysis would be suitable for the study of ornamental plants other than *Caladium*. Loh et al. is solely concerned with *Caladium* and the applicability of AFLPs to *Caladium* cultivars.

Caladium is a monocot and is entirely unrelated to the poinsettia, which is a dicot. One of ordinary skill in the art would not have considered results in distantly related plants, such as *Caladium* is to poinsettia, to be applicable to one another. The taxonomic relationship of poinsettia and *Caladium* is presented in a document identified as Appendix A, which was submitted concurrently with the response dated May 12, 2006 (copy attached at Appendix B). Further, this taxonomic relationship is discussed in detail in the Supplemental Declaration by Dr. Moyer under 37 C.F.R. § 1.132 (submitted concurrently with the response, dated May 12, 2006; hereinafter "the Moyer Supplemental Declaration") (copy attached at Appendix B).

As these documents show and as mentioned above, Caladium is not even in the same taxonomic class as poinsettia, that of the dicots. (Moyer Supplemental Declaration, para. 4). One of skill in the art would be well aware of the distant relationship between poinsettia and the reference plant, *Caladium*. As such, the work aimed at *Caladium*, as disclosed in the cited reference would have provided absolutely no motivation to one of skill in the art with respect to the present invention. Therefore, one of skill in the art would not have found the Appellants' achievement in poinsettia obvious in light of results in such a distantly related plant, alone or in any combination. In sum, Loh et al. does not suggest application of AFLP analysis to poinsettia to one of ordinary skill in the art. Loh et al. does not teach or suggest

that their findings could be applied broadly to other plants, much less to poinsettia in particular. Nor do they suggest that if tried, the ordinary person of skill in the art would have had a reasonable expectation of success.

Additionally, contrary to the assertion in the Final Action, *Caladium* is not an asexual ornamental plant but rather new cultivars of *Caladium* are developed by hybridization. *See* Loh et al., page 155, first paragraph. *Caladium* is asexually reproduced for the purpose of propagation of the various cultivars for commercial sale, but sexual reproduction is used to develop new cultivars. *Id.* A hybrid is defined as "offspring of two parents that differ in one or more heritable characteristics; offspring of two different varieties or of two different species (*see* Raven et al., *Biology of Plants*, Worth Pub., N.Y., N.Y. (1992), page 747) (copy of page 747, submitted concurrently with the response dated May 12, 2006). Hybridization leads to much greater genetic diversity than does asexual reproduction and thus, as a result of hybridization, each new *Caladium* cultivar would be relatively genetically diverse as compared to any plant that is asexually reproduced, such as poinsettia.

The Final Action further states:

> Loh et al. teach a method of identifying particular C. bicolor cultivars as well as identifying new cultivars (see abstract) and therefore not all of the plants assayed by Loh et al. were propagated by hybridization and the genetic diversity of C. bicolor is narrow, as taught by Loh et al. (see figure 4).

Final Action, page 19.

Appellants respectfully disagree with the interpretation of the Loh et al. abstract. The portion of the abstract that is referenced in the Final Action specifically states that "[t]he use of AFLP has potential for precisely characterizing and identifying particular caladium cultivars as well as for the registration of new cultivars." (Loh et al., Abstract, emphasis added). Clearly, this statement has nothing to do with how cultivars of *Caladium* are developed and cannot be construed to mean that the plants of Loh et al. were reproduced by any means other than hybridization as is stated in the text of the publication. *See* Loh et al., page 155, first paragraph. Nowhere does Loh et al. indicate that caladium cultivars are developed any way other than through hybridization.

Furthermore, nothing in Loh et al. states that the " genetic diversity of C. bicolor is narrow." Figure 4 of Loh et al. shows a UPGMA cluster analysis of AFLP data for the caladium cultivars. The data from Table 4 were used for the UPGMA cluster analysis. These

data show the genetic diversity estimates to be about 0.2 for all cultivars. Nowhere in Loh et al. is this described as narrow. In fact, other researchers looking at genetic diversity estimates of other plant species have not necessarily considered such a number to reflect narrow genetic diversity. (e.g., Osman et al. *Plant Physiology* 131: 1294-1301 (2003))

In contrast to *Caladium*, genetic variation in poinsettia is achieved by selection of sports (defined as a sudden deviation from type: a mutation) or naturally occurring or induced mutations (which are primarily radiation-induced mutations) rather than by breeding techniques such as hybridization. As a result, the genetic base of poinsettia is very narrow. One of ordinary skill in the art would not have concluded that the methods of Loh et al. with *Caladium* would have had a reasonable expectation of success if applied to an asexually reproduced and thus, much less genetically diverse plant, such as poinsettia.

Prior to the studies described in the present application, it would not have been at all obvious that AFLP fingerprinting analysis could be successfully applied to poinsettia (*see* Moyer Declaration, para. 5). As Dr. Moyer points out, although there were some reports of AFLP analysis in other ornamental plants, one of ordinary skill in the art would remain uncertain from these studies whether there would be sufficient inter-cultivar diversity among poinsettias tobe detectable by AFLPs (*Id.* at para. 5).

This lack of an expectation of success is further emphasized by Dr. Moyer's research using microsatellite simple sequence repeat (SSR) analysis with poinsettia. This research and its outcome were reported in the Moyer Declaration (para. 8-13). Dr. Moyer found that SSR analysis failed to differentiate poinsettia cultivars. *Id.* at para. 12-14. SSR analysis should have worked as well or even better than AFLP analysis since SSR markers tend to have a higher level of heterozygosity and a generally greater level of somatic stability than AFLP markers. *Id.* at para.13. SSR analysis has been shown to be applicable to a variety of plant species with success in determining genetic relationships. (*See* Pejic et al., *Theor. Appl. Genet.* 97:1248-1255 (1998) and Russell et al., *Theor. Appl. Genet.* 95:714-722 (1997); submitted concurrently with the response dated May 12, 2006). Thus, assuming, arguendo, as in the Final Action, and all previous Office Actions, that one of ordinary skill in the art would have had a reasonable expectation of success using AFLP analysis on poinsettia based on prior art using the AFLP method with other plant species, then it would also be assumed that one of ordinary skill in the art would have a reasonable expectation of success using SSR analysis in poinsettia. However, as shown in Dr. Moyer's data, the approach using SSR

analysis failed in poinsettia. From his data, it appears that the narrow genetic base of poinsettia lacks polymorphisms in the SSR loci. (*see* Moyer Declaration, para. 13). Thus, with this result in mind, it would be clear to one of ordinary skill in the art that the use of such technologies as SSR, RFLP, RAPD, AFLP, etc. to distinguish between and among poinsettia cultivars would not have been obvious. Accordingly, success using such technologies in poinsettia would be uncertain and that each would need to be tried out empirically.

In response to appellants' presentation of these data to the Examiner, the Final Action asserts that SSR analysis is not as sensitive a technique as AFLP (implying that it is not unexpected that SSR analysis would not work but one would still expect that AFLP analysis to be successful). Appellants disagree with this assertion. Any conclusion that one technique is more sensitive than another needs to be made on a species by species basis. In fact, Russell et al., in their report comparing the levels of genetic variation among barley accessions detected by RFLPs, AFLPs, SSRs and RAPDs, state "[I]ndeed, whenever SSRs have been compared to other systems, they have always revealed the highest levels of polymorphisms." (Russell et al., *Theor. Appl. Genet.* 95:714-722 (1997); page 719, first full sentence; copy enclosed herewith in the Evidence Appendix B; copy originally submitted concurrently with the response dated May 12, 2006). For this point they cite to the work of seven other research groups. Additionally, Pejic et al. found that among all of the methods tested, including SSR, RFLP, AFLP and RAPD, "the SSR data provided the highest level of discrimination between any pair of inbreds." Pejic et al., Theor. *Appl. Genet.* 97:1248-1255 (1998); page 1251, last full sentence; copy enclosed herewith in the Evidence Appendix B; copy originally submitted concurrently with the response dated May 12, 2006). Pejic et al. further state that "[T]he present data indicate on average SSRs carry two-fold more information that AFLPs and RAPDs." (Pejic et al., page 1251; second full paragraph). Therefore, Appellants respectfully submit that it is clearly incorrect to make the generalization that SSRs are less sensitive than AFLPs. Accordingly, in view of the foregoing, Appellants reassert that one of ordinary skill in the art could not have had any reasonable expectation of success prior to the present invention that sufficient polymorphisms detectable by AFLP would exist among poinsettia cultivars (Moyer Declaration, para. 6).

In further response to Appellants' arguments that it was uncertain whether there would be sufficient inter-cultivar diversity among poinsettias that would be detectable by AFLPs,

the Final Action states that "several articles reveal AFLP analysis was capable of detecting very similar genomic variations at the time the application was filed." Final Action, page 19. The articles that the Final Action cites are publications in which AFLP analysis is performed on isolates of *Bacillus anthracis* and *Escherichia coli*, both bacteria.

One of ordinary skill in the art wishing to analyze genetic diversity within a population of complex multicellular eukaryotes such as plants would not consider publications applying AFLP analysis to bacteria to be at all relevant. These organisms are not in the same taxonomic kingdom; one group is prokaryotic and the other eukaryotic. The genetic complexity of plants as compared to bacteria is dramatically different, with plants being many times more complex. One of ordinary skill in the art would not look to AFLP analysis of bacteria for guidance in performing AFLP analysis in a plant. Nor would such publications provide one of ordinary skill in the art any reasonable expectation of success as to application of AFLP technology to plants, much less specifically to poinsettia. As discussed previously, even AFLP analysis using different plants has little relevance to whether the application of that technology to any particular plant would be successful. Publications regarding bacteria would have even less relevance. Furthermore, in contrast to the assertion in the Final Action, one of the cited bacterial references, Arnold et al., states that the population of bacterial strains studied was "a genetically diverse group" (Arnold et al., page 1274, last sentence to page 1275, first sentence). The other reference, Keim et al., states that "the advantage of this system was the ability to screen a large number of potentially diverse strains across a relatively large percentage of the *B. anthacis* genome." (Keim et al., page 216, para. 1). Thus, it is not clear that these references even stand for the proposition made in the Final Action, that AFLP analysis was capable of detecting very similar genomic variations at the time the application was filed. Therefore, in view of the foregoing, Appellants assert that one of ordinary skill in the art could not have had any reasonable expectation of success prior to the present invention that sufficient polymorphisms detectable by AFLP would exist among poinsettia cultivars.

The Court of Appeals for the Federal Circuit has held that "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Furthermore, what is required under 35 U.S.C. § 103 is an "as a whole" assessment of the invention which further requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the

same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the prior art and combined them in the claimed manner. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004), see also *Princeton Biochemicals, Inc., v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1337 (Fed Cir. 2005). These criteria are not satisfied by the outstanding obviousness rejection. Simply identifying all of the elements in a claim in the prior art does not render a claim obvious. *Ruiz v A.B. Chance Co.*, 357 F.3d at 1275.

At most, the combination of the Ling et al., Loh et al. and Dice would have made it obvious to try to apply AFLPs to poinsettia cultivars. However, "obvious to try" is not the legal standard for obviousness under section 103. In the absence of any suggestion or demonstration whatsoever in any of the cited references that AFLP analysis would be appropriate for the study of poinsettias and given the lack of any close relationship between poinsettia and the plants studied in the cited references, there could have been no reasonable expectation of success with respect to the present invention. Thus, the teachings of Ling et al. in view of Loh et al. as defined by Dice would have provided neither the motivation to combine nor a reasonable expectation of success to one of ordinary skill in the art with respect to the present invention, both of which are legally required to maintain the outstanding rejection.

In view of the foregoing, Applicants respectfully submit that the claimed subject matter is nonobvious over Ling et al. in view of Loh et al. as defined by Dice, and respectfully request that the outstanding rejection under §103(a) be withdrawn.

III. Claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Barcaccia et al. (*J. Horticultural Science and Biotechnology* 74:243-50, (1999)) as defined by Dice et al.

The Final Action dated August 2, 2006 has maintained the rejection of claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69 as allegedly unpatentable under 35 U.S.C. § 103(a) over Ling et al. in view of Barcaccia et al., as defined by Dice. The Ling et al. reference has been addressed above and in the prior response and in the Moyer Declaration. The deficiencies of Ling et al. are not remedied by the teachings in Barcaccia et al. concerning *Pelargonium* or the analytical methods of Dice. The AFLP work in *Pelargonium* reported by Barcaccia et al. is not relevant to poinsettias, and would not have provided the motivation or reasonable

expectation of success with respect to the claimed invention that are legally required to maintain the present rejection.

As a preliminary matter, applicants note that *Pelargonium* or geranium is taxonomically unrelated to poinsettia. The taxonomic relationship of poinsettia and geranium is presented in a document identified as Appendix A, which was submitted concurrently with the response dated May 12, 2006 (copy attached at Appendix B). Further, this taxonomic relationship is discussed in detail in the Moyer Supplemental Declaration (copy attached at Appendix B).

As these documents show poinsettia and geranium are in entirely different taxonomic orders, with poinsettia being in the *Euphorbiales* and geranium being in the *Geraniales*. *Id.* As Dr. Moyer states, in the Order *Euphorbiales*, alone, the diversity of the plants represented is enormous much less when one starts comparing plants inside the *Euphorbiales* order to those outside, such as the *Geraniales*. (Moyer Supplemental Declaration, para. 8). One of ordinary skill in the art would have recognized the enormous differences between geranium and poinsettia and would not have found the application of AFLP analysis to geranium to teach, suggest or motivate one to apply AFLP analysis to the poinsettia. *Id.* at para. 8-9. Further, even if tried, the work with AFLPs and geranium would have failed to provide to one of ordinary skill in the art a reasonable expectation of success in its application to poinsettia, due to the recognition of the very distant relationship between the two species. *Id.*

Additionally, it should be noted that the data in Barcaccia et al. was generated using a very small number (ten) of geranium plants of entirely unknown genetic origin. The only information available about these plants is phenotypic, which appears to divide nine of the plants into two populations; the very same populations that the AFLP analysis detects. The tenth plant was a decayed flower from which no certain phenotypic data could be gotten and this fell into a third AFLP grouping. Barcaccia et al. presents no evidence that any of these plants represented different cultivar populations at all. There is simply no information as to the genetic similarity or dissimilarity of the plants used. Without any information on the genetic background of the plants used for the analysis, one of ordinary skill in the art would not have concluded based on Barcaccia et al. that AFLP analysis was successful in distinguishing even geranium cultivars, much less that the same technique could be applied successfully to distinguish between and among poinsettia cultivars. At most, one could say that this group of ten geraniums fell into three apparent groupings but since nothing is known

about the plants nothing can be said regarding the ability of the technique to distinguish geranium cultivars.

In response to this argument the Final Action states:

> The response has been thoroughly reviewed but not found persuasive. It is noted that the claims are drawn to a method of estimating a genetic relationship and the claims do not require that genetic origin of the plant be known.

Final Action, page 23.

Appellants respectfully submit that this is incorrect. In fact, independent claims 1, 3, 63, and 69 recite that the plant to which the poinsettia plant is being compared be either "known" or be "a representative member of a specific breeding family" (which would require that the representative member's breeding be known). In order to be able to make any statement regarding the ability of a particular technique to estimate a genetic relationship, to assess the breeding history, to determine whether one particular plant is a representative of a known cultivar or to distinguish between one cultivar from another known cultivar, it is necessary to have information regarding the genetic origin of the reference plant(s). Accordingly, because Barcaccia et al. utilizes only geranium plants of entirely unknown genetic origin, one of ordinary skill in the art would not have concluded, based on Barcaccia et al., that AFLP analysis was successful in distinguishing even geranium cultivars, much less that the same technique could be applied successfully to distinguish between and among poinsettia cultivars.

The Final Action states that Barcaccia et al. was not cited for its relationship to poinsettia. However, Appellants contend that the outstanding rejection draws a direct connection between work in geranium and the present invention in poinsettia. Final Action, page 22. This rejection is based on the premise that there would have been motivation to combine work done in geranium (Barcaccia et al.) with work done in poinsettia (Ling et al.), and, further, that the use of AFLP analysis in geranium would render obvious the use of AFLP analysis in poinsettia (this is the same premise upon which every obviousness rejection in the present case is based). Appellants' arguments regarding the distinctness of geranium and poinsettia are directed to the legally deficient foundation of the outstanding rejection; because there is no genetic relationship between geranium and poinsettia, (1) there would be no motivation to combine the cited references, and (2) even if the references were so combined there would not have been any reasonable expectation of success with respect to the present

invention. Accordingly, the outstanding rejection over Ling et al. in view of Barcaccia et al. and Dice is legally insufficient to establish a *prima facie* case of obviousness and should be withdrawn.

Finally, the Final Action states:

> The response asserts that Barccaccia did not evaluate the breeding history of the plant because breeding history refers to methods that provide information regarding the pedigree of the plant. This response has been reviewed but is not found persuasive as the claims do not require the pedigree of the plant. Furthermore, Barcaccia et al. teach using AFLP markers to identify the genetic relationship (identity vs. diversity) (breeding history) between a found flower and another plant (see page 244, 1st column, 2nd full paragraph). Therefore, Barcaccia et al. teach using AFLP markers to identify the breeding history of a plant (the found flower to a known plant). Therefore, Barcaccia et al. teach using AFLP markers to evaluate the breeding history of an asexual plant.

Final Action, pages 26-25.

Appellants reiterate that forensic work of Barcaccia et al. in comparing a found geranium flower of unknown origin with another geranium plant of unknown origin did not "evaluate the breeding history" of the plant as recited in claim 3 of the present application. Evaluation of the breeding history as used in the present invention refers to methods that provide information regarding the pedigree of the plant, for example, whether a plant is "essentially derived" from another plant or whether the reference plant was otherwise part of the pedigree of the new plant. One of the unexpected discoveries of the present inventors was that the presently claimed invention can be used to evaluate breeding history. None of the cited references, including Barcaccia et al., give any inkling whatsoever that AFLP analysis, or any other genetic analysis technique, can be used to evaluate breeding history in any plant, much less poinsettia as presently claimed. The plants used in the Barcaccia et al. study are of unknown genetic origin. Thus, the breeding history of these plants was not known and the breeding history of the unknown flower could not have been determined from these unknown plants. As a result, one of ordinary skill in the art would not consider Barcaccia et al., or any of the other cited references, as providing any teaching or suggestion that AFLP analysis, or any other genetic analysis technique, could be used to evaluate breeding history in any plant, much less poinsettia as presently claimed, wherein a plant is compared to another plant that is a representative member of a specific breeding family and is therefore known.

For the reasons set forth above, it is respectfully submitted that claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69 are patentable over Ling et al. in view of Barcaccia et al. as defined by Dice and appellants respectfully request that this rejection be withdrawn.

IV. **Claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Sukhwinder et al. (*Crop Improvement* 25:15-20 (1998)) as defined by Dice et al.**

The Final Action dated August 2, 2006 has maintained the rejection of claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69 as allegedly unpatentable under 35 U.S.C. § 103(a) over Ling et al. in view of Sukhwinder et al. as defined by Dice. The Ling et al. reference has been addressed in detail above and in the Moyer Declaration. The deficiencies of Ling et al. are not remedied by the teachings in Sukhwinder et al., which concerns rice, or by the analytical methods of Dice. The AFLP work in rice reported by Sukhwinder et al. is not relevant to poinsettias and would not have provided the motivation to combine or any reasonable expectation of success with respect to the claimed invention that are legally sufficient to maintain the present rejection. As Dr. Moyer states, rice is entirely unrelated taxonomically to poinsettia. (Moyer Supplemental Declaration, para. 5). They are not even in the same taxonomic class, as rice is a monocot and poinsettia is a dicot. (Supplemental Moyer Declaration, para. 4). One of ordinary skill in the art would not consider results in such distantly related plants, such as rice is to poinsettia, to be applicable to one another. *Id.* at para. 9.

Additionally, in view of the unpredictability of genetic fingerprinting in poinsettia (discussed previously in detail above on page 11, second full paragraph through page 12, first sentence, and in the Moyer Declaration, para. 15), the use of AFLPs in poinsettias would not have been at all obvious to one of ordinary skill in the art based on Ling in view of Sukhwinder's work and further in view of the methods of Dice prior to the present invention.

In light of the discussion above, it is respectfully requested that the obviousness rejection over Ling et al. in view of Sukhwinder et al. as defined by Dice be withdrawn.

V. **Claims 1, 3, 5, 6, 21, 23, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Barker et al. (*Genome* 42:173-183 (1999)) as defined by Tulloss (Offprint from Palm and Chapel, eds., (1997)).**

The Final Action has also maintained the rejection of claims 1, 3, 5, 6, 21, 23, 30, 63 and 69 as allegedly unpatentable under §103(a) over Ling et al. in view of Barker et al. as defined by Tulloss. The Ling et al. reference has been addressed in the preceding sections of this Appeal Brief and in the Moyer Declaration. The discussions in Barker et al. regarding willow and/or the analytical methods of Tulloss et al. do not remedy the deficiencies of the Ling et al. reference. Again, the AFLP work in willow reported by Barker et al. is not relevant to poinsettias and would not provide the requisite motivation or any reasonable expectation of success with respect to the present invention. Willow trees are unrelated taxonomically to poinsettia. (Moyer Supplemental Declaration, para. 7). They are in entirely different taxonomic subclasses, with willow in the *Dillenitidae* subclass and poinsettia in the *Rosidae* subclass. *Id.* at para. 7-8. One of ordinary skill in the art would not consider results in such distantly related plants, such as willow tree is to a poinsettia plant, to be applicable to one another. *Id.* at para. 9.

Additionally, in view of the unpredictability of genetic fingerprinting in poinsettia (discussed in detail above on page 11, second full paragraph, through page 12, first sentence, and in the Moyer Declaration, para. 15), the use of AFLPs in poinsettias could not have been at all obvious to one of ordinary skill in the art based on Ling in view of Barker's work and further in view of the methods of Tulloss prior to the present invention.

Accordingly, it is submitted that the present invention is patentable over Ling et al. in view of Barker et al. as defined by Tulloss, and request that the outstanding rejection under §103(a) on this basis be withdrawn.

In light of the entire record and the above discussion, Applicants respectfully submit that claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69 are patentable over Ling et al. in view of Loh et al, Barcaccia et al., Sukhwinder et al or Barker et al. as defined by Dice or Tulloss. Accordingly, Applicants respectfully request reversal of the pending rejection of claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69 and that this case be passed to issuance.

Respectfully Submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office at Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 20, 2007 via facsimile number (571) 273-8300.

Katie Wu

TABLE OF AUTHORITIES

CASES

STATUTES

Attorney Docket No. 5051-445

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Moyer et al.
Application No.: 09/912,072
Filed: July 24, 2001
For: *Identification of Poinsettia Cultivars*

Confirmation No.: 3267
Group Art Unit: 1634
Examiner: S. Bausch

Date: August 20, 2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Appendix A

CLAIMS APPENDIX

What is claimed is:

1. (Previously presented) A method of estimating a genetic relationship between a poinsettia plant and a known poinsettia cultivar, the method comprising the steps of:

(a) obtaining a DNA fingerprint of the poinsettia plant's genomic DNA by AFLP, the fingerprint comprising a collection of amplified polymorphic restriction fragments;

(b) comparing the fingerprint obtained in (a) with a genomic DNA fingerprint of the known poinsettia cultivar; and

(c) estimating the genetic relationship between the plant and the cultivar by determining the degree of similarity between the fingerprints.

2. (Previously presented) The method of Claim 1, wherein the amplified polymorphic restriction fragments comprise DNA sequences that include DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

3. (Previously presented) A method of assessing the breeding history of a first poinsettia plant, comprising:

(a) obtaining a DNA fingerprint of the genomic DNA of a first poinsettia plant by AFLP, wherein the fingerprint comprises a set of amplified polymorphic restriction fragments;

(b) comparing the fingerprint of the first poinsettia plant with a fingerprint of the genomic DNA of a poinsettia plant that is a representative member of a specific breeding family, wherein the fingerprint comprises a set of amplified polymorphic restriction fragments; and

(c) generating a profile index value based on the comparison of the fingerprint of the first poinsettia plant with the fingerprint of the poinsettia plant that is a representative member of a specific breeding family, thereby assessing the breeding history of a poinsettia plant.

4. (Previously presented) The method of Claim 3, wherein the amplified polymorphic restriction fragments comprise DNA sequences that include DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

5. (Previously presented) The method of Claim 3, wherein the specific breeding family is selected from the group consisting of the Freedom, Peterstar, and Sonora breeding family.

6. (Original) The method according to Claim 3, wherein the AFLP analysis is carried out by first digesting the genomic DNA with a restriction enzyme that has a tetranucleotide recognition site and a restriction enzyme that has a hexanucleotide recognition site.

7. (Original) The method according to Claim 6, wherein the restriction enzyme that has a tetranucleotide recognition site is *Mse*I, and the restriction enzyme that has a hexanucleotide recognition site is *Eco*RI.

8-9 (Canceled).

10. (Previously presented) The method of Claim 3, wherein the fingerprint of the genomic DNA of the first poinsettia plant is used to generate a profile of the poinsettia plant, wherein the profile comprises the set of amplified polymorphic restriction fragments that comprise DNA sequences that include the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37;** and wherein (b) comprises comparing the profile of the poinsettia plant to a profile generated from the fingerprint of the poinsettia plant that is a representative member of a specific breeding family, wherein the profile of the poinsettia plant that is a representative member of a specific breeding family comprises the set of amplified polymorphic restriction fragments that comprise DNA sequences that include the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35** and **37.**

11. (Previously presented) The method of Claim 10, wherein the profile of at least one of the first poinsettia plant and the profile of the poinsettia plant that is a representative

member of a specific breeding family is stored in a database comprising profiles of known poinsettia cultivars, and wherein the profiles of the known poinsettia cultivars comprise the set of amplified polymorphic restriction fragments that comprise DNA sequences that include the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

12-20 (Canceled).

21. (Previously presented) A method of determining the profile similarity of a first poinsettia plant to a second poinsettia plant, comprising:

(a) obtaining a DNA fingerprint of the genomic DNA of a first poinsettia plant by AFLP, wherein the fingerprint comprises a set of amplified polymorphic restriction fragments;

(b) comparing the fingerprint of the first poinsettia plant with a fingerprint of the genomic DNA of the second poinsettia plant, wherein the fingerprint comprises a set of amplified polymorphic restriction fragments; and

(c) generating a profile index value based on the comparison of the fingerprint of the first poinsettia plant with the fingerprint of the second poinsettia plant, thereby estimating the profile similarity of the first poinsettia plant to the second poinsettia plant.

22. (Previously presented) The method according to Claim 21, wherein the amplified polymorphic restriction fragments comprise DNA sequences that include DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

23. (Original) The method according to Claim 21, wherein the AFLP analysis is carried out by first digesting the genomic DNA with a restriction enzyme that has a tetranucleotide recognition site and a restriction enzyme that has a hexanucleotide recognition site.

24. (Original) The method according to Claim 23, wherein the restriction enzyme that has a tetranucleotide recognition site is *MseI*, and the restriction enzyme that has a hexanucleotide recognition site is *Eco*RI.

25-26 (Canceled).

27. (Previously presented) The method of Claim 21, wherein the fingerprint of the genomic DNA of the first poinsettia plant is used to generate a profile of the poinsettia plant, wherein the profile comprises the set of amplified polymorphic restriction fragments that comprise DNA sequences that include the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and 37; and wherein (b) comprises comparing the profile of the poinsettia plant to a profile generated from the fingerprint of the second poinsettia plant, wherein the profile of the second poinsettia plant comprises the set of amplified polymorphic restriction fragments that comprise DNA sequences that include the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35, and 37.**

28. (Previously presented) The method of Claim 27, wherein the profile of at least one of the first and the second poinsettia plants is stored in a database comprising profiles of known poinsettia cultivars, and wherein the profiles of the known poinsettia cultivars comprise the set of amplified polymorphic restriction fragments that comprise the DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

29. (Original) The method according to Claim 28, wherein the database is stored in a computer-readable storage medium.

30. (Original) The method according to Claim 21, wherein the comparing step is carried out by a computer.

31-51 (Canceled).

52. (Previously presented) The method of claim 64, wherein the comparison between the profile of the poinsettia plant and the known poinsettia cultivar is carried out by a computer.

53--62 (Canceled).

63. (Previously amended) A method of determining whether a poinsettia plant is a representative of a known poinsettia cultivar, comprising:

(a) obtaining a DNA fingerprint of the genomic DNA of a poinsettia plant by AFLP analysis; and

(b) comparing the fingerprint of (a) with a fingerprint of the genomic DNA of the known poinsettia cultivar;

wherein the poinsettia plant is a representative of the known poinsettia cultivar if the fingerprint of the poinsettia plant and the fingerprint of the known poinsettia cultivar have the same complement of polymorphic bands.

64. (Previously presented) The method according to Claim 63, wherein the DNA fingerprint of the genomic DNA is a set of amplified polymorphic restriction fragments, and wherein the amplified polymorphic restriction fragments comprise DNA sequences that include DNA sequences **SEQ ID NOS: 12, 20, 21, 22, 23, 24, 34, 35,** and **37.**

65-68 (Canceled).

69. (Previously presented) A method of distinguishing a poinsettia cultivar from a known poinsettia cultivar, comprising:

obtaining a DNA fingerprint of the genomic DNA of a poinsettia plant by AFLP analysis and;

comparing the fingerprint of (a) with a fingerprint of the genomic DNA of the known poinsettia cultivar;

wherein the poinsettia plant is not a representative of the known poinsettia cultivar if the fingerprint of the poinsettia plant and the fingerprint of the known poinsettia cultivar are not essentially the same.

70. (Canceled).

71. (Canceled).

72. (Canceled).

73. (Canceled).

74. (Canceled).

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Appendices B & C

In re: Moyer et al.
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Filed: July 24, 2001

EVIDENCE APPENDIX

Evidence listing:

1) Document entitled "APPENDIX A. Taxonomic relationships between poinsettia and the plant species in the cited references." This document was submitted concurrently with the response dated May 12, 2006.

2) Document entitled "Moyer Supplemental Declaration". This document was submitted concurrently with the response dated May 12, 2006 as a 1.132 declaration by Dr. James Moyer.

3) Document entitled "Moyer Declaration." This document was submitted concurrently with the response dated May 23, 2005 as a 1.132 declaration by Dr. James Moyer.

4) Document entitled "Appendix I." This document was submitted concurrently with the 1.132 declaration by Dr. James Moyer (entitled "Moyer Declaration") and the response dated May 23, 2005

5) Raven et al., *Biology of Plants* Worth Pub., N.Y., N.Y. (1992), page 747. A copy of page 747 was submitted concurrently with the response dated May 12, 2006.

6) Pejic et al., Theor. *Appl. Genet.* 97:1248-1255 (1998). A copy of Pejic et al. was submitted concurrently with the response dated May 12, 2006

7) Russell et al., *Theor. Appl. Genet.* 95:714-722 (1997). A copy of Russell et al. was submitted concurrently with the response dated May 12, 2006.

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RELATED PROCEEDINGS INDEX

(none)